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8 UNITED STATES DISTRICT COURT

9 DISTRICT OF ARIZONA

10 In Re Bard IVC Filters Products
 11 Liability Litigation

12 No. MD-15-02641-PHX-DGC

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 15 **PLAINTIFFS' RESPONSE TO
 DEFENDANTS C.R. BARD, INC.'S
 AND BARD PERIPHERAL
 VASCULAR, INC.'S MOTION TO
 EXCLUDE THE OPINIONS OF
 DAVID GARCIA, M.D. AND
 MICHAEL STREIFF, M.D.**

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 17 Plaintiffs oppose Defendants' Motion to Exclude the Opinions of David Garcia,
 18 M.D. and Michael Streiff, M.D. ("Motion" or "Mot.") [Doc. 7294]. Plaintiffs incorporate
 19 in this response their Omnibus Statement of Law and Generally-Applicable Arguments in
 20 Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert*
 21 ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set
 22 forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

23 **I. INTRODUCTION**

24 Dr. David Garcia and Dr. Michael Streiff ("the Experts") are experienced Medical
 25 Directors of Anti-Thrombotic Therapy and Professors of Hematology at prestigious
 26 medical hospitals who employed reliable methodology using standard, well-accepted
 27 methods of their discipline to reach negligence, design defect, and failure to warn
 28 opinions that will assist the trier of fact. Utilizing their extensive education, knowledge,

1 training, and experience, the Experts reached their opinions by performing their
2 independent review of the available published, peer-reviewed literature on IVC filters,
3 Bard's Instructions For Use documents ("IFU"), Bard's internal documents, Bard's
4 witness depositions, and by reviewing the expert report of David Kessler, M.D.

5 The Experts, in general, offer opinions regarding the risk-benefit assessment of
6 IVC filters; the Experts address the lack of efficacy for IVC filters as well as
7 hematological aspects of this litigation. Because the Experts are well-qualified to offer
8 these opinions and their opinions are methodologically reliable, they should be admitted
9 to aid the jury with their testimony.

10 **II. QUALIFICATIONS**

11 The Experts are physicians and well-known board-certified hematologists. Their
12 practice includes advising and caring for patients who have blood disorders or deficiencies
13 focusing on the management of venous thromboembolism. Over the past two decades, the
14 Experts have published dozens of studies on the management of venous
15 thromboembolism ("VTE"), which is the diagnosis, treatment, and prevention of VTE,
16 including the appropriate use of vena cava filters and anticoagulant medications.

17 David Garcia, M.D. is currently the Medical Director of Anti-Thrombotic Therapy
18 and Professor of Hematology at University of Washington. Dr. Garcia received a B.A. in
19 physics from Duke University in 1989 and his M.D. from University of Alabama School
20 of Medicine in 1993. He completed his residency at John Hopkins Hospital in 1996 and
21 his fellowship in Hematology at the University of Washington in 2013. Dr. Garcia has
22 taught in the field of Hematology since 2008.

23 Dr. Garcia's clinical practice, research and teaching have focused on hematologic
24 disease, largely the treatment and prevention of venous thromboembolism. During his
25 twenty (20) years of practicing medicine, teaching students or trainees, and writing
26 industry guidelines, Dr. Garcia has reviewed between fifty (50) and a hundred (100)
27 papers relevant to the safety and/or efficacy of IVC filters. A key focus of Dr. Garcia's
28 non-clinical duties has been the design, conduct, and appraisal of clinical research.

1 Dr. Garcia has treated patients who suffered from IVC filter complications,
2 including duodenal penetration, device migration to the right atrium, and acute IVC
3 occlusion due to thrombus, and he has been part of the decision-making process in which
4 the risks and benefits of implantation or removal of IVC filter were weighed.

5 Michael Streiff, M.D. is currently the Medical Director of the Johns Hopkins
6 Hospital Anticoagulation Service and a Professor of Hematology at John Hopkins
7 University. Dr. Streiff, M.D. received a B.S. in biology from Washington and Lee
8 University in 1983. He was selected to be Fulbright Scholar in biochemistry at the
9 University of Ulm, Germany in 1984. He earned his M.D. from John Hopkins University
10 in 1988. He completed his residency at the University of Florida in 1991 and his
11 fellowship in Hematology/Oncology at The John Hopkins University in 1997. Dr. Streiff
12 has taught in the field of Hematology since 1997.

13 Since 2000, Dr. Streiff's clinical research has focused on the management of
14 venous thromboembolism including the appropriate use of vena cava filters. He has
15 written several widely-cited articles and book chapters on vena cava filters and
16 participated in the writing of several guidelines on management of VTE and vena cava
17 filters. In addition, Dr. Streiff teaches residents and fellows as well as medical students on
18 an ongoing basis about benign hematology including management of VTE.

19 Both Experts have published peer-reviewed manuscripts in numerous journals,
20 including the *New England Journal of Medicine*, *Blood*, *Annals of Internal*
21 *Medicine*, *Thrombosis and Hemostasis*, *Journal of Thrombosis Research*, and *Journal*
22 *Thrombosis and Hemostasis*, and served as peer reviewers for these publications.

23 Dr. Garcia is a member of the editorial board of the journal *Thrombosis*
24 *Research* and the Special Section Editor for the journal *Blood*.

25 The Experts' report is attached to the Motion as Exhibit A. Their curriculum vitae
26 and list of reliance materials are also included within Exhibit A as Appendices A and C.

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1 **III. ARGUMENT**

2 **A. The Experts Are Qualified to Render Opinions in the Field of**
 3 **Hematology That Relate to the Risks/Benefits of Bard IVC Filters and**
 4 **Physician Expectations.**

5 Bard mistakenly implies that only physicians involved in the implanting and
 6 removal of IVC filters can offer opinions on physician expectations. (*See* Mot. at 5.) This
 7 assumption fails to take into consideration the multidisciplinary medical teams typically
 8 involved in patient care, starting with the physicians who “order” and “recommend”
 9 patients to have filters implanted. On a daily basis, Drs. Garcia and Streiff make clinical
 10 decisions regarding the diagnosis, treatment, and prevention of venous thromboembolism.
 11 Their practices focus on the management of venous thromboembolism, including a risk-
 12 benefit assessment of the use of vena cava filters and anticoagulant medication. (*See*
 13 Mot., Ex. A, Rep. p. 2-4; Ex. 1, Garcia Dep., June 21, 2017, 53:5-54:22; 55:3-13; 100:14-
 14 103:9; Ex. 2, Streiff Dep., July 12, 2017, 101:23-102:9.)¹

15 Physician expert witnesses routinely opine about “standard of care medicine” and
 16 what a “reasonable doctor” would have done or expected in a particular situation in
 17 medical malpractice and many other types of litigations.² Drs. Garcia and Streiff testify
 18 from their experiences as clinicians; in order for them to make reasonable risk-benefit
 19 assessments regarding filters, it is critically important that manufacturers of IVC filters,
 20 like Bard, continuously apprise the clinicians who order and implant IVC filters about
 21 their safety profile, performance characteristics, design problems, and internal risk
 22 assessments. (*See* Mot., Ex. A, Rep. p. 7; Ex. 1, Garcia Dep. 192:22-194:2; Ex. 2, Streiff
 23 Dep. 276:8-24; 277:4-16.) Bard’s arguments are without merit. Complete transparency
 24 about the safety profile of its IVC filters is paramount to physician expectations.³

25 ¹ Q: ...you are involved in the decision for patients about whether to recommend or not an
 26 IVC filter? A: Very often. (Ex. 1, Garcia Dep. 54:8-11.)

27 ² Indeed, Arizona law requires such testimony as a predicate for filing a medical
 28 malpractice action or any other lawsuit against a licensed professional. *See* A.R.S.
 29 §§ 12-2602, -2603.

30 ³ Dr. Garcia was asked if medical device companies should provide risk assessments to
 31 physicians: “they need to publicly disclose it -- I mean, whether it’s to regulators or to

1 Even Bard's own expert and several corporate witnesses adopt the position that the
 2 expectations of physicians are paramount when it comes to safety and efficacy, and in
 3 making risk-benefit/informed consent decisions.⁴ Bard's Chris Ganser, V.P. of Quality
 4 Assurance, testified, "I want doctors to have as much information as possible to make an
 5 informed decision how to use the product." (Ex. 6, Ganser Dep. Oct. 11, 2016, 208:2-22.)

6 Bard cites no authority to support its argument.⁵ The type of expert testimony
 7 required for a product liability case involving failure to warn is no different than in a
 8 medical malpractice case, particularly on the subject of informed consent. In both cases
 9 the expert witness is offering his or her opinion on how a doctor should or would respond
 10 to a certain situation. And the foundation for a medical expert's opinion is the same,
 11 including professional guidelines, clinical experience and education, peer-reviewed
 12 literature, and interactions with colleagues in the relevant community. *See Primiano v.*
 13 *Cook*, 598 F.3d 558, 567 (9th Cir. 2010) (holding that admitting physician's testimony
 14 must be admitted based on his background, experience, and explanation of his opinion).
 15 Rule 702/*Daubert* could never be used to justify the exclusion of an expert's standard of
 16 care opinions in a medical malpractice case—or a lawyer expert's standard of care

17 practicing physicians. But somebody needs to know about it." (Ex. 1, Garcia Dep.
 18 196:19-22.) "And if a company is getting reports from far and wide of complications --
 19 which are maybe happening infrequently at any given institution, but with some frequency
 20 in the world at large -- they're the only entity that has the ability to provide that
 21 perspective to an individual physician, who is him or herself just only able to focus on
 22 what's going on in their immediate surroundings." (Ex. 1, Garcia Dep. 198:4-11.)
 23 Dr. Streiff agrees it is an expectation in the medical community that companies that
 24 provide medical devices will put patient safety first and paramount. (Ex. 2, Streiff Dep.
 25 319:3-7.)

26 ⁴ Christine Brauer, Bard's regulatory expert and former Bard consultant, testified "it is
 27 important for a medical device manufacturer to understand healthcare professionals'
 28 expectations for performance of a product." (Ex. 3, Brauer Dep., Aug. 2, 2017, 334:4-14.)
 29 Len DeCant, former Bard V.P. of Research and Development, testified he agreed that a
 30 company has an obligation to disclose to doctors all information available for doctors to
 31 make a determination on whether to use the product. (Ex. 4, DeCant Dep., May 24, 2006,
 32 304:10-17.) John DeFord, Bard Sr. V.P. of Science, Technology and Clinical Affairs,
 33 testified physicians should be able to make "the risk/benefit has to be evaluated in every
 34 device." (Ex. 5, DeFord Dep., June 2, 2016, 130:20-131:1-8.).

1 opinion in a legal malpractice case—just because the physician or lawyer expert couldn’t
 2 point to a peer-reviewed study of physicians or lawyers nationwide to support their
 3 opinion. *See, e.g., Saint Alphonsus Med. Ctr.- Nampa, Inc. v. St. Luke’s Health System,*
 4 *Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL 407446, at *18 (D. Idaho Jan. 24, 2014)
 5 (basing conclusion of law on defense expert’s testimony that “all physicians” at the
 6 defendant-hospital needed to obtain access to the hospital’s electronic health record
 7 system in order to perform their duties).

8 As practicing hematologists, Drs. Garcia and Streiff make determinations on
 9 whether to “order” or “recommend” the placement of Bard IVC filters on a routine basis.
 10 For the Experts to practice “standard of care medicine”, this is the very information they
 11 require to make a risk/benefit assessment and, here, to decide not to utilize a Bard IVC
 12 filter.⁶ The Experts meet the requisite legal standard and are well-qualified to opine on
 13 physicians’ expectations to properly assess the risks versus the benefits of IVC filters
 14 along with other available therapies.

15 **B. The Experts’ Opinions Are Based on Sound Methodology.**

16 The methodology used by the Experts is well-established in their discipline.
 17 (See Mot. Ex. A, Rep. p. 2-4, 10, Addendum, Appendix A and C.) The Experts’ report
 18 describes this methodology: a systemized study of over 200 peer-reviewed published
 19 articles (including their own studies); Bard’s IFU documents, internal documents, and
 20 witness depositions; and Dr. Kessler’s report and Dr. Asch’s Study all collectively served
 21 as the foundation of their analysis. (*Id.*; *see also* Ex. 1, Garcia Dep. 21:6-22:3.) The
 22 Experts’ opinions satisfy the reliability requirement of *Daubert* and Rule 702 because they
 23 are based on a sound methodology that employs reason, data, and the methods of his
 24 discipline. The best indicia of reliability of an expert’s methodology is whether it is
 25

26
 27 ⁶ “...I think we wanted to emphasize it here, because when you have an intervention --
 28 the benefit or efficacy of which is highly questionable or poorly established -- ensuring
 that the doctors who are choosing to use it [Bard IVC filters] know as much detail as
 possible about its risks, has heightened importance.” (Ex. 1, Garcia Dep. 193:10-15.)

1 deemed reliable outside of the courtroom. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.
 2 137, 152 (1999).

3 1. The Experts' Opinions Based on Dr. Kessler's Report Are Reliable as
Experts Are Permitted to Base Their Opinions in Part on Other
Experts' Testimony.

5 Drs. Garcia and Streiff examined Dr. Kessler's Rule 26 report when developing
 6 their own opinions. There is nothing improper about doing so. To make it appear that
 7 Drs. Garcia and Streiff adopted Dr. Kessler's opinions and "regurgitated" them as their
 8 own in violation of Fed. R. Evid. 703, Bard selects out-of-context sound bites from their
 9 deposition testimony. Bard mischaracterizes both the factual record and the law.

10 In complex cases where the parties offer opinions of multiple experts, it is not
 11 uncommon for an expert to base an opinion in part on the testimony of other expert
 12 witnesses with more specialized knowledge. *In re Toyota Motor Corp. Unintended*
13 Acceleration Mktg., Sales Practices, and Prods. Liab. Litig., 978 F. Supp. 2d 1053, 1066
 14 (C.D. Cal. 2013). Such testimony is admissible as long as the expert does not merely act
 15 as a conduit for the other expert's opinion. *Id.* The Experts' report satisfies these
 16 requirements.

17 The Experts do not rely solely on the opinions of Dr. Kessler, however. The
 18 Experts culled through a considerable volume of medical literature on IVC filters in
 19 compiling their own reference list of relevant article. (See Mot. Ex. A, p. 1-4, Appendix A
 20 and C.) They also considered their own published, peer-reviewed research and that of
 21 their colleagues. (*Id.*) They combined this data with their own professional knowledge
 22 and clinical experience with IVC filters, as well as their personal experience and
 23 interactions with physicians in other medical disciplines relating to the use of with IVC
 24 filters. (Ex. 1, Streiff Dep. 316:9-317:6.) The Experts supplemented their report with a
 25 one-and-a-half page Addendum after having "the opportunity to read Dr. David Kessler's
 26 report based upon his review of documents relevant to the ongoing national litigation and

1 medical monitoring class action suit against Bard.” (See Mot. Ex. A. p. 8-9.)⁷
 2 Dr. Kessler’s report “highlighted additional risks associated with the Bard products that
 3 were not necessarily publically known about or available to practicing doctors and were
 4 relevant in the overall risk/benefit discussion that my report entailed.” (Ex. 1, Garcia Dep.
 5 210:16 – 211:2.) As stated in the Addendum, the Experts assessment was based upon
 6 “data provided in his [Dr. Kessler’s] summary” and led them to reach their conclusions
 7 that Bard “did not fulfill their own internal performance standard and would pose an
 8 increased risk adverse events on patients.” (See Mot. Ex. A, Rep. p. 8-9.)

9 The fact that they agree with these opinions does not hinder the reliability of their
 10 analysis because it is consistent with their own research. *See In re Toyota*, 978 F. Supp.
 11 2d at 1071 (finding that plaintiff’s expert’s opinion was admissible because he reviewed
 12 other types of data, not solely the opinions of other experts.)⁸ Defendants’ assertion that
 13 the Experts “regurgitated” Dr. Kessler’s report is an exaggerated mischaracterization.
 14 They reviewed his report and the data within it in their entirety, including Dr. Asch’s
 15 study and Dr. Betensky’s calculations, and then judiciously summarized 7 out of 51
 16 opinions concerning the hematologic issue of venous pressure and migration resistance in
 17 order to supplement their own findings.⁹ (Ex. 1, Garcia Dep. 212: 8-17; Ex. 2, Streiff
 18 Dep. 294:13-17; 304:1-5; 316:9-317:6; 319:8-19.) The Experts “felt that it would provide
 19 important background information” and the “information stated in this addendum only

20

21 ⁷ Dr. Streiff spent five hours reviewing Dr. Kessler’s report alone, not including the
 22 additional time he spent drafting the Addendum. (Ex. 2, Streiff Dep. 295:13-17.)
 23 Dr. Garcia spent about 25 to 30 hours in total researching and drafting the report,
 24 including review of Dr. Kessler’s report and materials. (Ex. 1, Garcia Dep. 33: 9-12;
 25 204:9-20.)

26 ⁸ Even Bard’s own experts, Christine Brauer and Donna Tillman, testified they have no
 27 basis to dispute Dr. Kessler’s schedules and representation of Bard’s documents, and
 28 further they could not identify any Bard internal documents that contradict the referenced
 data that Dr. Kessler cites in his report. (Ex. 3, Brauer Dep.54:10-55:19; Ex. 7, Tillman
 Dep. Aug. 4, 2017, 98:5-19; 172:1-7.)

⁹ Dr. Garcia testified “I considered this addendum about Kessler’s report to be information
 that strengthens the rest of my report with Dr. Streiff.” (Ex. 1, Garcia Dep. 217:1-11; *See*
 also Ex. 1, Garica Dep. 204:9-20, 212:8-17.)

1 further highlights the risks of IVC filters beyond what I could have done using publicly
 2 available peer reviewed information that's cited in my report." (Ex. 1, Garcia Dep.
 3 204:21-25; 217:1-25.) The Experts used Dr. Kessler's opinions to further demonstrate not
 4 only that evidence of IVC filters' efficacy does not exist, but that Bard was aware of this
 5 fact. (Ex. 1, Garcia Dep. 202:12-25; Ex. 2, Streiff Dep. 304: 10-305:8.)

6 The Experts' evaluation of the documents supporting the opinions of Drs. Kessler
 7 satisfies any reliability concerns the Court may have about the Experts use, in part, of
 8 another expert's report. *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 556 (C.D. Cal.
 9 2014).

10 Bard's argument that the Experts rely too much on Dr. Kessler is best reserved for
 11 objection at trial. Cross-examination is the more appropriate vehicle to question an
 12 expert's credentials and methodology than exclusion under Rule 702. If it appears during
 13 direct examination that the Experts are simply "regurgitating" without any showing of
 14 expertise, Bard can object to the testimony and the Court can sustain the objection if it
 15 agrees. But the mere fact that many of Plaintiffs' experts reach similar conclusions based
 16 on the same evidence is not grounds for exclusion.

17 2. Dr. Garcia Employed Reliable, Accepted Methodology When
 18 Forming Opinions Specific to Bellwether Plaintiff Doris Jones.

19 Bard's allegation that Dr. Garcia did not employ a reliable methodology when
 20 reviewing Doris Jones's medical records is a misrepresentation of his testimony and
 21 report. Dr. Garcia's opinion is exactly the type of advice he provides to his patients in his
 22 daily practice and it is precisely within his area expertise to opine on the potential
 23 thrombotic effect of a foreign body inside the pulmonary artery.

24 Bard inaccurately states Dr. Garcia did rely on a medical literature or other
 25 scientific evidence" to support his opinion concerning Mrs. Jones' increased risk of a
 26 thrombotic event due to the presence of a foreign bod in her pulmonary artery; this is not
 27 true. Dr. Garcia's opinion is based on "the observations of IVC filters promoting
 28 thrombosis in randomized controlled trials, as well as in observational cohort studies, as

1 well as the observation that foreign bodies -- examples of which I cited to you earlier --
 2 catheters, prosthetic mechanical heart valves -- can promote -- do promote thrombosis.”
 3 (Ex. 1, Garcia Dep. 234:23-235:4; 236:25-237:15.)¹⁰ Rule 702/*Daubert* could never be
 4 used to justify the exclusion of an expert’s opinion because the expert cannot point to a
 5 peer-reviewed study to support their opinion. *See, e.g., Saint Alphonsus Med. Ctr.-*
 6 *Nampa, Inc. v. St. Luke’s Health System, Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL
 7 407446, at *18 (D. Idaho Jan. 24, 2014). Further, Dr. Garcia specifically states in his
 8 case-specific report that “in support of these opinions, I expressly incorporate my expert
 9 report.” (See Mot. Ex. B, Rep. p. 1-2.)

10 Next, Bard focuses on the fact that Dr. Garcia does not “quantify” the increased
 11 risk Mrs. Jones experiences; however, quantifying the risk is impossible. There is no way
 12 to quantify the risk “other than again extrapolating from what we know about intact
 13 filters.” (Ex. 1, Garcia Dep. 242:9-17.) Contrary to Bard’s analysis in their Motion,
 14 quantifying the risk is inconsequential as both Dr. Garcia and Bard’s own expert, Mark
 15 Moritz, M.D. agree a foreign body inside a critical vessel exposes Mrs. Jones to an
 16 *ongoing risk of harm* which is vulnerable to increase at any moment in time. (Ex. 1,
 17 Garcia Dep. 226:13-227:11; Ex. 8, Moritz Dep., July 18, 2017, 146:11-148:5; 150:14-
 18 152:24.)

19 It is true that, Dr. Garcia, a hematologist, and Bard’s expert, Dr. Moritz, a vascular
 20 surgeon, disagree on the necessity for indefinite anticoagulation for Mrs. Jones. But it is
 21 also true and important to note that Dr. Moritz testified he would consult with doctors in
 22 other medical disciplines, like a hematologist, regarding Mrs. Jones’ treatment. (Ex. 8,
 23
 24

25 ¹⁰ “I’ve cited clinical examples to you of those -- when they’re exposed to circulating
 26 blood, they activate factor XII, which is one of the clotting proteins that are involved in
 27 the so-called contact activation or intrinsic activation pathway. And that triggers a chain -
 28 - a series of chain reactions that ultimately can lead to the formation of a blood clot. And it’s entirely stimulated by contact with foreign surfaces. And I have no reason to think
 that a filter fragment would be an exception to a rule that’s certainly followed by many
 other foreign bodies.” (Ex. 1, Garcia Dep. 237:5-15)

1 Moritz Dep. 146:21 -147:2-12.)¹¹ Divergent medical opinions are not a basis for expert
 2 exclusion under *Daubert*. *See Daubert v. Merrell Dow Pharms.*, Inc., 43 F.3d 1311, 1318
 3 (9th Cir. 1995)

4 Dr. Garcia's analysis meets and exceeds the *Daubert* threshold for a scientifically
 5 valid method. "A trial court should admit medical expert testimony if physicians would
 6 accept it as useful and reliable," but it need not be conclusive because "medical
 7 knowledge is often uncertain." *Primiano v. Cook*, 598 F.3d 558, 565-66 (9th Cir. 2010),
 8 *as amended* (Apr. 27, 2010).¹² "More importantly, I can say to a reasonable degree of
 9 medical certainty that that filter strut being there --irrespective of by what mechanism -- is
 10 putting Ms. Jones at increased risk of thrombosis at that site and distal to it." (Ex. 1,
 11 Garcia Dep. 234:1-22; *See Mot. Ex. B, Rep. p. 1-2.*) When evaluating the expert
 12 testimony of physicians in particular, courts should broadly admit medical expert
 13 testimony if it is useful and reliable "but it need not be conclusive because medical
 14 knowledge is often uncertain." *Primiano*, 598 F.3d at 565 (quotation marks omitted).
 15 "Where the foundation is sufficient, the litigant is entitled to have the jury decide upon the
 16 experts' credibility, rather than the judge." *Id.* (alterations and quotation marks omitted.)

17 _____
 18 ¹¹ Bard also misconstrues Dr. Garcia's testimony regarding anticoagulation therapy for
 19 Mrs. Jones. (*See Mot.* at 7.) Dr. Garcia never wavered on the need for anticoagulation,
 20 his testimony was in response to being asked by Bard about the risks involved in
 21 anticoagulation therapy, to which he responded, "I think it's fair to stay I can't fully assess
 22 the risk of anticoagulation therapy in her, because I don't have some of those details."
 23 (Ex. 1, Garcia Dep. 223:4-21.)
 24 ¹²

25 Medicine is not a science but a learned profession, deeply rooted in a
 26 number of sciences and charged with the obligation to apply them for man's
 27 benefit. Evidence-based medicine is the conscientious, explicit and
 28 judicious use of current best evidence in making decisions about the care of
 individual patients. Despite the importance of evidence-based medicine,
 much of medical decision-making relies on judgment—a process that is
 difficult to quantify or even to assess qualitatively. Especially when a
 relevant experience base is unavailable, physicians must use their
 knowledge and experience as a basis for weighing known factors along with
 the inevitable uncertainties to mak[e] a sound judgment.

29 *See id.* (quoting *Cecil Textbook of Medicine* 1 (James B. Wyngaarden & Lloyd H. Smith
 30 Jr. eds., 17th ed.1985) and *Harrison's Principles of Internal Medicine* 3 (Dennis L.
 Kasper et al., 16th ed. 2005); (alterations and quotation marks omitted.)

1 Dr. Garcia applied the same methodology in arriving at his opinion in this litigation
2 that he applies on the front lines in caring for many patients who have received IVC
3 filters. Dr. Garcia provides reliable case-specific opinions for Mrs. Jones, including his
4 opinion that “the presence of foreign body in her pulmonary artery branch represents a
5 significant risk factor for the development of a in situ thrombosis;” which is based upon
6 sound methodology he employs in his daily practice as a hematologist. As such, Bard
7 assertions do not warrant the exclusion of Dr. Garcia’s qualified and reliable opinions. If
8 Bard believes Dr. Garcia’s opinions are unreliable because Bard does not agree that
9 Mrs. Jones has an increased risk of a thrombotic event, it may address this concern during
10 its cross-examination as is commonly done. But ruling out Dr. Garcia’s case-specific
11 opinions as unreliable based at this stage is unwarranted and premature.

12 | IV. CONCLUSION

13 Based on the foregoing reasons, Plaintiffs respectfully request that the Court deny
14 in full all of Bard's motions to exclude opinions of Drs. Garcia and Streiff.

15 || RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti